IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

In re Seroquel XR (Extended Release Quetiapine Fumarate) Antitrust Litigation	Master Docket No. 20-1076-CFC
This Document Relates to:	
All Actions	

MEMORANDUM ORDER

These class actions arise out of a 2011 agreement to settle a patent lawsuit relating to extended-release quetiapine fumarate, an anti-psychotic drug sold by Defendants AstraZeneca Pharmaceuticals LP and AstraZeneca LP (collectively, AstraZeneca) under the brand-name Seroquel XR® (Seroquel). AstraZeneca had alleged in the underlying lawsuit that generic versions of Seroquel made by Defendant Handa Pharmaceuticals LLC and other generic manufacturers were covered by one of AstraZeneca's patents and that abbreviated new drug applications (ANDAs) filed by Handa and the other manufacturers with the Federal Drug Administration (FDA) to market their respective generic versions of Seroquel constituted patent infringement under the Hatch-Waxman Act. *See* 35 U.S.C. § 271(e)(2)(A) (making the submission of an ANDA "an act of

infringement . . . for a [generic] drug claimed in a patent or the use of which is claimed in a patent" for the brand drug).

Although the patent's expiration date was May 28, 2017, AstraZeneca was entitled to an additional six-month period of the patent's exclusivity under 21 U.S.C. § 355 because of AstraZeneca's participation in pediatric studies of Seroquel. D.I. 627 ¶ 4; D.I. 718 ¶ 4. Thus, as long as the patent remained valid, it effectively precluded a manufacturer from marketing before November 28, 2017 a generic version of Seroquel that infringed the patent unless that manufacturer had a license from AstraZeneca.

As part of an agreement to settle its case against Handa, AstraZeneca paid Handa $4 million in cash, licensed the asserted patent exclusively to Handa as of November 2016 (i.e., a year before the patent's pediatric exclusivity period ended), and agreed not to launch its own generic version of Seroquel during the 180-day period in which only Handa and AstraZeneca had FDA approval to lawfully market a generic version of Seroquel—thus ensuring that the only generic version of Seroquel on the market during that period would be sold by Handa, which enjoyed a 180-day period of exclusivity as the generic first filer. D.I. 718 ¶ 59; D.I. 627 ¶¶ 16–17; *see also FTC v. Actavis, Inc.*, 570 U.S. 136, 143–44 (2013) (explaining that the first generic manufacturer to file with the FDA an ANDA to market a generic drug "will enjoy a period of 180 days of exclusivity" and that

"[d]uring that period of exclusivity, no other generic can compete with the brand-name drug"); *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 393 (3d Cir. 2015) (holding that "[t]he relevant statute permits the brand to produce an 'authorized generic' during the [first generic filer's] exclusivity period") (citations omitted).

Plaintiffs allege that these settlement terms constituted an unlawful "reverse payment"—i.e., a payment made *by the plaintiff* (AstraZeneca) *to the defendant* (Handa) to settle claims *brought by the plaintiff*—that delayed and suppressed competition among sellers of generic versions of Seroquel in violation of the Sherman Act, as interpreted in *Actavis*. Plaintiffs allege that as a result of this delay and suppressed competition, they paid more than they should have for branded and/or generic versions of Seroquel. D.I. 135 ¶ 25. And they say that the settlement agreement caused them this antitrust injury because, but for that agreement, AstraZeneca and Handa would have entered into an alternative settlement agreement that would have allowed Handa to launch a generic version of Seroquel in July 2015. *See* D.I. 635-1 at 22.

Plaintiffs base their causation theory on the opinions of their expert, Dr. Keith Leffler. Pending before me is Defendants' motion pursuant to *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993) "to exclude the modeling

opinions" of Dr. Leffler that are "set forth in ¶¶ 13(E)-(F), 92-108 of his Opening Expert Report and ¶¶ 2, 66-79 of his Reply Expert Report." D.I. 633.

I.

Federal Rule of Evidence 702 provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the proponent demonstrates to the court that it is more likely than not that:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case.

Fed. R. Evid. 702. In *Daubert*, the Supreme Court held that Rule 702 "imposes a special obligation upon a trial judge to 'ensure that any and all scientific testimony . . . is not only relevant, but reliable.'" *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999) (quoting *Daubert*, 509 U.S. at 589). In *Kumho Tire*, the Court held that "this basic gatekeeping obligation" "applies to all expert testimony," and not just "scientific" testimony. *Id.*

II.

Defendants summarize Dr. Leffler's alternative settlement opinions in relevant part as follows:

> Dr. Leffler purports to calculate a range of mutually acceptable licensed-entry dates for AstraZeneca and Handa in a hypothetical negotiation removing the alleged "reverse payment" to Handa . . ., changing only the licensed entry date with respect to AstraZeneca's patent . . . . Dr. Leffler also purports to isolate "a reasonable estimate" of the single licensed entry date the parties would have agreed on in 2011, in this case, July 1, 2015.
>
> To calculate what licensed entry dates the parties allegedly would have found acceptable in this supposed alternative settlement, Dr. Leffler calculates the benefit to AstraZeneca and Handa of various alternative licensed entry dates. Dr. Leffler then compares the benefit of these various alternative settlements to the benefit of continuing to litigate instead. Under his model, if both parties' benefit from settlement with a particular licensed-entry date exceed their benefit from continued litigation, he assumes both parties would find that licensed-entry date acceptable.

D.I. 634 at 2–3 (citations omitted). Plaintiffs do not dispute this summary.

Defendants argue that Dr. Leffler's model "is inadmissible in this case because it does not 'reflect[] a reliable application of [Dr. Leffler's] principles and methods to the facts of the case.'" D.I. 634 at 3 (alterations in the original) (quoting Fed. R. Evid. 702(d)). Specifically, Defendants say that Dr. Leffler's application of the model to the facts of this case is unreliable because Dr. Leffler used Handa's overall expectation of success in the underlying patent case (80%) and not Handa's different expectations of success with respect to its noninfringement (70%) and invalidity defenses (20% for each of two such

defenses) in that case to calculate what licensed entry dates Handa would have found acceptable in an alternative settlement. D.I. 634 at 2–4.

At least at first blush, there appears to be some force to Defendants' critique of Dr. Leffler's reliance on Handa's overall 80% expectation of success. As Dr. Leffler himself acknowledged in a deposition, Handa stood to profit more if it prevailed at trial only on its noninfringement defense as opposed to if it prevailed on either or both of its invalidity defenses. D.I. 635-1 at 46 (Tr. 190:12–15). A verdict in favor of Handa only on infringement would have allowed Handa—but not other generic manufacturers—to enter the market. A verdict in Handa's favor on either of its invalidity defenses, however, would have opened the door for other generics to enter the market once Handa's 180-day FDA exclusivity period had run.

Plaintiffs counter in their briefing that "[a]ny differences in Handa's expected number of competitors would not affect [Dr. Leffler's] ultimate opinion on the alternative no-payment entry date" and that "[a]ccordingly, [Dr. Leffler] did not need to separately model the chances of winning on invalidity or noninfringement." D.I. 714 at 2. Plaintiffs flesh out this argument with these words:

> If Handa did not expect other generics to establish noninfringement or enter via their own settlements, the value of both [the expected value of continued litigation and the expected value of settling] would increase

> because Handa would not expect generic competition after its exclusivity period until AstraZeneca's patent expired. Conversely, if Handa expected the patent to be found invalid, multiple subsequent generics might enter after Handa's exclusivity, which would reduce the value of *both* the settlement and continued litigation.
>
> Accordingly, to properly modify Dr. Leffler's model to include separate chances of invalidity and noninfringement, it would be necessary to revise both the expected value of settlement *and* the expected value of continued litigation (not just the expected value of continued litigation as in Dr. Garibotti's analysis). But no change is necessary because, as Dr. Leffler determined, use of the overall chance of success necessarily produces a no-payment entry date that is not materially different from a more complex model using separate odds.

D.I. 714 at 3 (emphasis in the original). In this same vein, Plaintiffs state later in their briefing that

> different expectations about Handa winning on invalidity versus noninfringement could impact the number of expected generic entrants resulting from a Handa win. However, such changes in the number of generics *do not* materially change the expected entry date generated by [Dr. Leffler's] model because they impact *both* the expected value of litigation *and* the expected value of settlement, the values that determine the economically acceptable no-payment entry date in Dr. Leffler's model.

D.I. 714 at 5–6 (emphasis in the original) (citations omitted).

I have to say that I cannot make sense of Plaintiffs' argument. If the number of generic manufacturers would have "impact[ed]" both Handa's expected value of

continued litigation and Handa's expected value of settlement, it follows that for "the number of generics to not materially change the expected entry date," "the impact" the number of generic manufacturers in the market would have had on Handa's expected value of continued litigation must be the same (or at least not materially different from) "the impact" the number of generic manufacturers would have had on Handa's expected value of settlement. There is, however, nothing in Plaintiffs' briefing that explains (1) how the number of generic manufacturers in the market would have impacted Handa's expected value of continued litigation; (2) how the number of generic manufacturers on the market would have impacted Handa's expected value of settlement; or (3) how is it that any change in the number of generic manufacturers on the market would have had the same (or at least a not materially different) impact on Handa's expected value of continued litigation that it would have had on Handa's expected value of settlement?

I dedicated much of the nearly seven-hour oral argument I held on the parties' outstanding *Daubert* and summary judgment motions to this motion and to this issue in particular. *See generally* D.I. 825. And yet, having heard argument, reviewed the transcript of the argument, and studied again for many hours Plaintiffs' briefing in opposition to this motion, I remain unable to understand Plaintiffs' argument. I am tempted to grant Defendants' motion for that reason.

But I will not do so—at least not at this time. I base that decision on Dr. Leffler's statement in his reply report that "[t]he only way that separately modeling the impact of non-infringement versus invalidity impacts [his] model is if a different number of generics were expected depending upon whether Handa won on validity or non-infringement" and that he "used [in his model] the same number of generic entrants regardless of whether Handa won on validity or non-infringement" because that "is consistent with the forecasts of AstraZeneca and Handa, which are the proper evidence for modeling an alternative no-payment settlement agreement reached in September 2011." D.I. 715-3 ¶ 71 (footnotes omitted). Dr. Leffler also stated in his opening report that he "found that the number of expected generic entrants does not materially change the alternative settlement entry date." D.I. 715-1 ¶ 103 n.146.

It seems to me that the dispositive questions that govern this motion are (1) whether it was reasonable for Dr. Leffler to use in his model "the same number of generic entrants regardless of whether Handa won on validity or non-infringement" and (2) whether it was reasonable for him to have "found that the number of expected generic entrants does not materially change the alternative settlement entry date." And it seems to me the prudent course is to convene a hearing at which Plaintiffs can call Dr. Leffler to the stand to answer these

questions and Defendants can cross-examine Dr. Leffler to test the reasonableness of his answers.

NOW THEREFORE, at Wilmington on this Nineteenth day of February in 2025, it is HEREBY ORDERED that the Court will convene on March 11, 2025 at 9:00 a.m. in Courtroom 4B a hearing, during which the parties may present evidence to aid the Court in its resolution of Defendants' motion "to exclude the modeling opinions" of Dr. Leffler that are "set forth in ¶¶ 13(E)-(F), 92-108 of his Opening Expert Report and ¶¶ 2, 66-79 of his Reply Expert Report" (D.I. 633). Dr. Leffler is required to testify at the hearing and shall be subject to cross-examination by Defendants. Defendants may, but are not required, to present their own witness or witnesses.

CHIEF JUDGE